REMARKS

These remarks are in response to the Office Action mailed January 29, 2008. Claims 33-40 has been amended. The amendment to claim 33 is supported in original claim 33; Applicants have merely rearranged the terms to better clarify the claimed invention. Claims 34-40 have been amended to make the preamble in each dependent claim consistent with the independent claim.

Applicants respectfully directed the Examiner to the issued claims in parent Application No. 09/699,131, and to the Examiner's Amendment and reasons for allowance in the parent application. In particularly, the claimed subject matter of claim 33, upon which the remaining claims depend, is directed to the compositions used in the method of parent application no. 09/699,131, which Examiner Cook indicated as allowable. No new matter is believed to have been introduced.

I. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 33-40 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

The Office Action, mistakenly indicates that "various different proteins can be encoded by the *same* nucleotide sequence. . ." (Emphasis in original, see, e.g., the office action at page 3, part 4A). Actually, it is the exact opposite that is true; i.e., a single polypeptide can be encoded by multiple different nucleotide sequence due to the degeneracy of the genetic code; however, the same frame of nucleotide sequences provides the same polypeptide sequence. Applicants respectfully direct the Examiner to the sequence submission of June 4, 2001, in the parent application (now U.S. Patent No. 6,716,410) and the sequence listing submitted concurrently with the filing of the present application on November 12, 2003. The sequence listing provides the nucleotide sequence and the corresponding amino acid "encoded by" the sequence of SEQ ID NO:1 and of SEQ ID NO:2 for each of the light and heavy chains, respectively. Thus, Applicants submit that the claims are clear and definite. Applicants respectfully request that the Examiner reconsider the sequences

providing the structural information of the humanized antibody of claim 33 (upon which the remaining claims depend). Accordingly, Applicants respectfully request withdrawal of the rejection.

The Office Action further indicates that "fragment antibody and single chain fragment" is vague and indefinite because it is unclear as to what the terms will encompass. Applicants have amended claim 33, upon which the remaining claims depend, to more clearly set out the claimed invention. Furthermore, Applicants submit that the terms "fragment antibody (Fab)" and "single chain fragment (scFv)" are well known in the art at the time of filing of the present application. For example, the terms are found in patents having filing dates as early as 1994. Accordingly, Applicants respectfully request withdrawal of the rejection.

II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 33-40 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the Office Action alleges that the specification is not enabled for the claimed antibodies because the instant specification is not in compliance with the biological deposit rules. Applicants respectfully traverse this rejection.

A deposit is one way of enabling a biological material, however, enablement can also be satisfied by describing how to make and use the claimed invention absent a deposit. In a series of office actions and responses in the parent application, the issue of enablement of IK17 in the absence of a deposit was addressed. The sequences and specification provide sufficient description to enable the presently claimed invention. For example, passages that support the enablement of the disclosure include, but are not limited to:

- "IK17 was isolated form a phage display library prepared from RNA from PMNCs from a donor with coronary heart disease." (p. 6, line 9-10).
- "The cDNA was used as a template for PCR amplification of the light and heavy chains, as described previously (Barbas and Lerner, 1991). Subsequently 3 pairs of extension primers were used for secondary

amplification to add restriction sites to each of the three classes of fragments, V-kappa, V-lambda and VH." (p. 6, lines 23-27).

- "Plasmid DNA containing the VH and VL genes of the FAb was isolated from cells and sequence using an automated sequencer. . . . Analysis revealed that the repertoire of the Fab of the invention light chain uses a V-kappa family 3 gene (Vg/38k/L6) with the rearrangement Jk2. The repertoire of heavy chain uses a VH3 family gene, 3-23/VH26c/DP47, with the rearrangement JH4b." (p. 7, lines 13-19).

The Applicants submit that the phage display method only displays variable chains and these sequences are sufficient to define the binding specificity of the antibody in whatever form, Fab, scFv or antibody. No antibody constant regions are displayed during the screening process and are not required for the specificity of binding. For example, a library of variable regions generated by PCR are cloned into a phage expression vector which provides appropriate spacing between the variable regions so that they may act as if they were in the context of an antibody. It was agreed by the Examiner, in the parent application, that the structure of antibodies are well known to those skilled in the art. The Applicants submit that an advantage of the phage display method was that it allows the identification of variable chains that could be inserted into any desired backbone to generate binding sites for the epitope of the antibody or different species specific antibodies. The contexts into which such variable chains can be included are well known to those skilled in the art.

As pointed out to the Examiner during prosecution of the parent case, there is a distinction between the monoclonal antibody of the present invention and phage display from a monoclonal antibody identified by testing antibodies secreted by hybridoma cell lines that could require a deposit to enable the antibody. The Examiner had previously agreed that the distinction was logical and stated that a deposit would not be required to enable the antibody of the invention (see, e.g., the response filed in 09/699,131 on August 29, 2003). Subsequently, the application was allowed.

The pending claims are consistent with the Examiner's statement in the parent case, provide both structure and function, methods of making and using the

claimed invention. For at least the foregoing reasons, Applicants respectfully request withdrawal of the rejection.

Claims 33-40 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Office Action alleges the description does not set forth "any sequence" by which the claimed fragments can be determined. Applicants respectfully traverse this rejection.

Applicants respectfully direct the Examiner to the sequence listing filed in the present application and as recited in the claims. Furthermore, at the time the application was filed, Applicants provided a sequence listing encoding the Vk-light and Vk-heavy chains of the antibody IK17. Accordingly, the disclosure and claims provide a sequence by which the claimed fragments can be determined. Furthermore, the claims set forth the functional aspects of such fragments. Thus, Applicants provided both structural characteristics and functional characteristics demonstrating the possession of the invention at the time of filing. For at least the foregoing reasons, Applicants respectfully request withdrawal of the rejection.

For at least the foregoing, the Applicant submits that the claimed invention is patentable and request reconsideration and notice of such allowable subject matter.

The Director is authorized to charge any required fee or credit any overpayment to Deposit Account Number 50-4586, please reference the attorney docket number above.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

GAVRILOVICH, DODD & LINDSEY LLP

Date: June 27, 2008

By: /Joseph R. Baker, Jr./
Joseph R. Baker, Jr.
Registration No. 40,900

4445 Eastgate Mall, Suite 200
San Diego, California 92121
(760) 479-0474